

# CONTACT TONOMETER USING MEMS TECHNOLOGY

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention:

The present invention relates to the use of micro-electro-mechanical systems ("MEMS") technology in the fabrication of pressure or force sensing monitors for the human body in the medical field and, more particularly, for sensing intra-ocular pressure (IOP).

### 2. Brief Discussion of the Related Art:

The eye is one of the most important organs of the human body. It is hard to imagine how difficult and lonely it would be if you lost visual contact with the colorful world. Cataracts, glaucoma and age-related macular degeneration are the three major diseases of the eye that rob older people of vision. Among these three, glaucoma is the leading cause of blindness, accounting for 12 percent of new cases of blindness each year in the United States. Glaucoma is often called the "silent thief" because most people who develop glaucoma cannot feel it until it is too late to be mitigated by medical treatment.

The most significant indicator of glaucoma has been found to be elevated inner eye pressure. This elevated eye pressure damages the optic nerve and can deteriorate into total blindness for the patient. Accordingly, early detection is crucial for successful glaucoma treatment, and elevated inner eye pressure, or intra-ocular pressure ("IOP"), is the signature of glaucoma. The measurement of IOP has been the most effective diagnostic tool for early detection of glaucoma. Actual IOP can only be obtained through a direct method, such as inserting a cannula connected to a manometer into the anterior and posterior segments of the eye. It is obvious that this method cannot be used in routine eye examinations. Thus, IOP is measured non-invasively, which is defined as tonometry, during routine eye exams.

During the past century several tonometry methods have been established and

applied in clinical practice. The following is a brief history of tonometry methods:

- Early 1900: Schiøtz tonometer
- 1950s: Goldmann tonometer
- 1960s: MacKay-Marg tonometer
- 1970s: Non-contact tonometers
- 1980s: Handheld tonometers such as the Tono-Pen® applanation tonometer marketed by Medtronic Xomed, Inc., and portable Goldmann tonometers such as the Draeger or Perkins devices.

In the past, Tonometry was classified in general as two types according to the method of corneal distortion. They are:

- applanation tonometry - a small portion of cornea is flattened, and
- indentation tonometry - a small portion of cornea is "indented."

Indentation tonometry, represented primarily by the Schiøtz tonometer, was the dominant method to measure IOP during the first half of the last century. It gradually faded away after the Goldmann Applanation Tonometer ("GAT") was invented. The disadvantages of the Schiøtz tonometer were:

- patient apprehension,
- anesthesia required,
- good patient cooperation needed,
- corneal abrasions possible,
- required a physician (not staff members) , and
- significant aqueous displacement.

Applanation tonometry can be divided into two categories

- Variable force (constant area) contact applanation tonometry (GAT, MacKay-Marg tonometer ("MMAT"), Draeger tonometer, Perkins tonometer, and Tono-Pen® applanation tonometer, and
- Constant force (variable area) applanation tonometry (non-contact ).

1 The major IOP measurement method currently is variable force applanation contact  
2 tonometry.

3 The (IOP) is constantly above the atmospheric pressure to preserve the shape of  
4 the eyeball, thereby ensuring a stable alignment of the optical components. There are  
5 two separate compartments inside the eye: the aqueous cavity and the vitreous cavity.  
6 The front compartment (aqueous cavity) is filled with a fluid called aqueous. Within the  
7 aqueous cavity are two areas: the anterior chamber (in front of the iris) and the posterior  
8 chamber (behind the iris). The vitreous cavity is filled with a jellylike substance called  
9 vitreous.

10 While the vitreous is relatively inert and stable, the aqueous humour serves to  
11 provide the metabolic oxygen demands of the lens and a portion of the cornea, both  
12 without blood vessels. Additionally, the vitreous plays a key role in maintaining IOP by  
13 balancing formation and drainage rates of aqueous humour and to act, in the anterior  
14 chamber, as a component of the optical system.

15 Aqueous is produced by the ciliary bodies and pumped into the posterior  
16 chamber, where it circulates through the papillary space and into the anterior chamber.  
17 It drains out of the anterior chamber through the trabecular meshwork and reaches  
18 Schlemm's canal. It is then transported through a network of aqueous veins and  
19 gradually absorbed into the blood supply by vessels in the conjunctiva. If the flow of  
20 aqueous is impeded along its route, IOP will rise which can damage the optic nerve.

21 Statistical mean IOP is 16 mmHg with a standard deviation of 3 mmHg. Although  
22 there is no clear line between safe and unsafe IOP, it is commonly called elevated IOP  
23 when the IOP exceeds 21 mmHg. Many factors can affect the IOP, such as time of the  
24 day, heartbeat, respiration, exercise, fluid intake, systemic medications, topical drugs,  
25 cannabis and alcohol (transient decrease), caffeine (transient increase), recumbent  
26 position (higher), aging (higher), and genetics.

27 There are two basic forms of glaucoma, closed-angle glaucoma and open- angle

1 glaucoma. Closed-angle glaucoma occurs where the root of the iris blocks the route  
2 where aqueous flows into the trabecular meshwork. Open-angle glaucoma occurs  
3 where the trabecular meshwork is clogged. Open-angle glaucoma is the more common  
4 form. Beyond these two, it has been observed that some patients developed glaucoma  
5 despite having normal IOP (low tension glaucoma). The cause of this type of glaucoma  
6 is still unknown.

7 The Imbert-Fick law is the foundation of all types of applanation tonometers. It  
8 was introduced late in the last century and then applied to IOP measurement. However,  
9 it was widely accepted and became the dominant tonometry method only in the 1950s  
10 after the invention of the Goldmann applanation tonometer. In accordance with the  
11 Imbert-Fick law, if an infinitely thin, perfectly flexible, perfectly elastic, and dry spherical  
12 container with internal pressure  $P$  is flattened (applanated) by an external force  $W$ , the  
13 flattened area  $A$ , external force  $W$  and internal pressure  $P$  have the following  
14 relationship:

$$P_t = W/A.$$

16 The human eye does not satisfy all of the conditions required in the Imbert-Fick  
17 law in that the cornea is about 0.5 mm (mean value) thick rather than infinitely thin, the  
18 cornea tissue is not perfectly flexible and a small portion of the deforming force is  
19 balanced with the tension rather than IOP force. The cornea has limited rigidity rather  
20 than being perfectly elastic, the cornea is wet and the surface tension of the tear film  
21 tends to pull the applanating surface onto the cornea.

22 In 1957, Goldmann and Schmidt found through their experiments that the Imbert-  
23 Fick law could be more realistically presented in the IOP measurement by the equation  
24 where

$$W + s = P_t \times A_i + b$$

26 where

27  $W$  = external deforming force;

s = extra force due to surface tension tending to pull the applanating surface against the cornea;

$P_t$  = IOP;

$A_i$  = flattened area of cornea; and

b = force to bend the cornea.

Goldmann and Schmidt also found that s and b are balanced if the diameter of the applanation area is 3.06 mm. Therefore, the equation becomes

$$W = P_t \times \pi \times (3.06\text{mm})^2 / 4 = 7.35P_t$$

or

$$P_t = W / 7.25 \text{ g / mm}^2 = 10 W \text{ mmHg} .$$

Goldmann and Schmidt noted that the measurements are only reliable in eyes with normal human corneas. These equations are not valid in eyes of examined animals because the corneas of the animals' eyes are different from the human corneas.

The Goldmann Applanation Tonometer (GAT) was designed based on the experimental data from average thickness and rigidity of human corneas. When a cornea is thicker than average, the reading of GAT is higher than true IOP; when a cornea is thinner, the reading is lower. When the cornea is weakened, either by excimer ablation or by stromal edema the readings of GAT are always lower.

As mentioned above, the force to bend the cornea and the force due to surface tension cannot be neglected in the IOP measurement of human eyes. In 1959, Mackay and Marg invented a special applanation tip ("MMAT") where those forces are physically eliminated; therefore, the Imbert-Fick law can be directly applied to the IOP measurement. Unlike other tonometers, the Mackay-Marg applanation tip is formed of two areas. A central area (about 1-2 mm in diameter) is the sensing area. A force or

1 pressure sensor is implemented there. The central sensing area is surrounded by a  
2 guarding area (about 3 mm in diameter).

3 This type of design has the advantages of the force to bend the cornea does not  
4 affect the IOP measurement since bending is done by the guarding area. The surface  
5 tension of tears does not affect the IOP measurement since it happens in the  
6 conjunction of the guarding area and eyeball, there not being a need to carefully monitor  
7 the applanation to reach total flatness as in the case of GAT since only the central area  
8 is used to calculate the IOP, the tip being coverable by a disposable rubber membrane  
9 to reduce possibility of infection and also to protect both the tip and the eye. The central  
10 sensing part of the MMAT can be a plunger combined with a force sensor. It has been  
11 found through animal (rabbit) testing that there is an ideal initial plunger extension. For  
12 a 1.5-mm diameter plunger, a 5 micron initial projection is ideal.

13 During MMAT experiments, it has been observed that the MMAT tonograms  
14 share a common interesting format in rising sharply to the first crest dipping to a first  
15 trough, rising again slowly to a central maximum, dipping to a second trough, rising  
16 again to a second crest and then falling sharply to the baseline. This format is  
17 explained as the corneal bending effect during IOP measurement by MMAT: first crest,  
18 representing bending of the cornea at the limit of the applanated area, the first trough,  
19 representing balance of applanation force and IOP force, the central maximum  
20 representing raised pressure resulting from the applanation, and the depth of the trough  
21 representing a measure of corneal stiffness.

22 Findings from experiments with MMAT reveal that crests and troughs are  
23 prominent when the diameter of the transducer tip is under 2 mm and almost smoothed

1 to a plateau by 3 mm diameter, special precautions must be taken to place the  
2 tonometer squarely on the cornea to get correct IOP readings, ordinary 75 micron thick  
3 rubber films tend to degrade the crest by reducing sensitivity so that use of a thinner  
4 covering or none at all may be desirable for this purpose; and corneal bending rather  
5 than corneal buckling is responsible for the crest and trough of the curve.

6 A particularly effective and easy-to-use applanation tonometer is the Tono-Pen®  
7 applanation tonometer marketed by Medtronic Xomed, Inc. (Ophthalmic division) and  
8 described in U.S. Patent No. 4,747,296 to Feldon et al. The Tono-Pen® applanation  
9 tonometer is a portable, hand held instrument utilizing micro strain gauge technology  
10 with a 1.5 mm transducer tip. As described in the Feldon et al patent, the Tono-Pen®  
11 applanation tonometer has an elongate housing mounting an activation switch,  
12 batteries, a display, electronic circuitry and a microprocessor mounted on a printed  
13 circuit board and a strain gauge sensor/transducer. In use, the Tono-Pen® applanation  
14 tonometer is moved to contact the cornea and displays the average of four independent  
15 readings, along with a statistical coefficient, with accuracy comparable to the GAT.

16 Some of the areas where the Tono-Pen® and other applanation tonometers may  
17 be improved include reduced weight to facilitate use, the permitting of a more gentle  
18 contact with the cornea, ruggedness, such that the applanation tonometer can more  
19 easily withstand being dropped without permanent damage, ease of manufacture at  
20 bulk rates, repeatability of manufacture of the transducer/sensor as well as simplified  
21 manufacture of the applanation tonometer.

22 MEMS are miniature micro-electro-mechanical systems, sometimes referred to  
23 as miniature electromechanical components formed of micromachined transducers in

1 silicon, primarily, and often integrated with electronic microcircuits, herein referred to as  
2 "electronics." The transducers can be sensors and/or actuators based on  
3 electrostriction, electromagnetic, thermoelastic, piezoelectric, piezoresistive, capacitive,  
4 acoustic, strain gauge, differential pressure and/or optical effects. MEMS fabrication  
5 uses techniques previously used for microelectronics permitting accurate and bulk  
6 microfabrication such that MEMS devices provide enhanced performance and are  
7 resistant to failure due to corrosion and wear.

8 MEMS devices have been contemplated for use in the past for placement within  
9 the eye or on a contact lens to sense IOP due to their small size; however, the  
10 unexpected advantages of the use of MEMS technology in both hand held and table  
11 mounted tonometers have not been recognized nor has there been any recognition of  
12 the manner in which MEMS technology can be used to improve tonometers.

### 13 SUMMARY OF THE INVENTION

14 The present invention is generally characterized in a contact tonometer for  
15 sensing intra-ocular pressure (IOP) of an eye comprising a contact surface for making  
16 contact with a surface of said eye; a micro-electro-mechanical system (MEMS) device  
17 connected to said contact surface wherein said MEMS device produces an electrical  
18 signal corresponding to the force applied by said contact surface to said surface of said  
19 eye when said surface of said eye is contacted by said contact surface; an electronics  
20 unit for receiving said electrical signal and converting said electrical signal to an IOP  
21 signal that is representative of the IOP of the eye; a display for receiving the IOP signal  
22 from the electronics unit and displaying information that is representative of the IOP of  
23 the eye; and a power source for supplying electrical power to said electronics unit and



1 said display. In one embodiment, the contact tonometer is a hand held device. In  
2 another embodiment, the contact tonometer further comprises a first housing member  
3 capable of being attached to a human finger for containing the contact surface and the  
4 MEMS device. This first housing member may also contain the electronics, the display  
5 and the power source, or any combination thereof. In yet another embodiment, the  
6 contact tonometer further comprises a second housing member coupled to said first  
7 housing member and capable of being attached to a human hand for containing the  
8 display. This second housing member may also contain the electronics, the activation  
9 switch and the power source, or any combination thereof.

#### 11 BRIEF DESCRIPTION OF THE DRAWINGS

12 Fig. 1 is a schematic diagram of the contact tonometer of the present invention.

13 Fig. 2 is a perspective of acontact tonometer according to one embodiment of the  
14 present invention.

15 Fig. 3 is a side view, partly in section, of one embodiment of the contact  
16 tonometer of the present invention.

17 Fig. 4 is a side view, partly in section, of another embodiment of the contact  
18 tonometer of the present invention.

19 Fig. 5 is a side schematic view of an embodiment of the contact tonometer  
20 sensor of the present invention.

21 Fig. 6 is a side schematic view of another embodiment of the contact tonometer  
22 sensor of the present invention.

23 Fig. 7 is a side schematic view of another embodiment of the contact tonometer

1 sensor of the present invention.

2 contactcontactFig. 8a is a side schematic view of an embodiment of the contact  
3 tonometer sensor of the present invention.

4 Fig. 8b is a side schematic view of an embodiment of the contact tonometer  
5 sensor of the present invention when force is applied.

6 Fig. 9a is a side schematic view of an embodiment of the contact tonometer  
7 sensor of the present invention.

8 Fig. 9b is a side schematic view of an embodiment of the contact tonometer  
9 sensor of the present invention when force is applied.

10 Fig. 10a is a side schematic view of an embodiment of the contact tonometer  
11 sensor of the present invention.

12 Fig. 10b is a side schematic view of an embodiment of the contact tonometer  
13 sensor of the present invention when force is applied.

14 Fig. 11 is a schematic diagram of the distribution of charge in a piezoelectric  
15 material.

16 Fig. 12 is a schematic diagram of an embodiment of the contact tonometer  
17 sensor of the present invention.

18 Fig. 13 is a schematic diagram of an embodiment of the contact tonometer  
19 sensor of the present invention.

20 Fig. 14 is a schematic diagram of the cylinder driver and pickup of the  
21 embodiment of Fig. 13.

22 Fig. 15 is an electronic schematic diagram of the electronic circuit of the cylinder  
23 driver and pickup of the embodiment of Fig. 13.

1           Fig. 16 is a schematic diagram of an embodiment of the contact tonometer  
2 sensor of the present invention.

3           Fig. 17a is a schematic diagram of an embodiment of the contact tonometer  
4 sensor of the present invention.

5           Fig. 17b is a schematic diagram of the embodiment of the contact tonometer  
6 sensor of the present of Fig. 17a in a stressed condition.

7           Fig. 18 is a schematic diagram of one embodiment of the contact tonometer  
8 sensor of the present invention.

9           Fig. 19 is a schematic diagram of an embodiment of the contact tonometer  
10 sensor of the present invention of Fig. 18.

11           Fig. 20 is a perspective of a contact tonometer according to one embodiment of  
12 the present invention.

### 13           **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

14           As shown schematically in Fig. 1, contact tonometer 2 according to the invention  
15 includes a housing 4 having a distal or contact end 6 and, in a preferred embodiment, a  
16 gripping portion 8 proximal to the contact end 6. The contact tonometer 2 includes a  
17 MEMS device 10 acting as a transducer to measure the force applied by the contact  
18 end 6 to the patient's cornea and to produce an electrical signal representative thereof.  
19 The contact tonometer 2 includes electronics and/or microprocessor ("electronics") 12, a  
20 source of power 14 and a display 16. In the preferred embodiment, the electronics 12,  
21 source of power 14 and display 16 are integral parts of the housing 4. However, in  
22 another embodiment, they may be separate from housing 4.

23           Electronics 12 processes electrical signals from the MEMS device 10 and

1 supplies a signal to display 16 causing display 16 to display information representative  
2 of the determined IOP. The source of power 14 is connected to the electronics 12 and  
3 display 16 and provides power to the electronics 12 and display 16. An activation  
4 switch 18 is preferably disposed on the housing 4 and is connected to electronics 12.  
5 Activation switch 18 allows a user to activate the electronics 12. However, in another  
6 embodiment activation switch 18 may be separate from housing 4.

7 Source of power 14 is preferably a battery. However, the source of power 14  
8 could also be any other source of power such as common household electrical power  
9 provided through a power line. Where the source of power 14 is common household  
10 electrical power, the contact tonometer 2 will need to be connected to the source of  
11 common household power through a power cable (not shown) connected to such  
12 source of common household power as is well understood in the art. Additionally,  
13 where the source of power is common household power, the source of power 14 may  
14 include a power supply to provide an appropriate voltage to the electronics 12 and  
15 display 16. Where the source of power 14 is a battery, the battery may be, but is not  
16 required to be, mounted in the housing 4 in a manner to provide balance for the contact  
17 tonometer 2 as required.

18 Although a specific arrangement of and connection between the MEMS device  
19 10, electronics 12, source of power 14, display 16 and activation switch 18 has been  
20 described, it is clear that other configurations and connections may be used so long as  
21 the functionality of the components separately and combined is maintained. The  
22 following examples are given for the purpose of illustration and are not intended to limit  
23 the possible combinations and configurations that will be clear to those skilled in the art.

1 For example, activation switch 18 could be electrically located between the source of  
2 power 14 and the electronics 12 to control power being provided to electronics 12.  
3 Additionally, the MEMS device 10, electronics 12 and display 16 could all be connected  
4 by a bus that allows power and information to pass between the devices. Further, all or  
5 some of these devices could be formed together in an integrated device such as an  
6 integrated circuit (IC).

7 Electronics 12 includes any suitable electronics to take the signal sent from the  
8 MEMS device 10 and operate on such signal according to an algorithm such as that  
9 described above in connection with the Goldmann and Schmidt equation described  
10 above to correlate the force measured by the MEMS device 10 to IOP. Electronics 12  
11 preferably includes a microprocessor but may include application specific integrated  
12 circuits (ASIC) or hard-wired electronics. The signal processing described in the Feldon  
13 et al '296 patent and used in the Tono-Pen® contact tonometer is representative of one  
14 embodiment of the electronics 12 for use with the contact tonometer of the present  
15 invention.

16 The MEMS device 10 is connected to the contact end 6 through a connection  
17 member 20. Connection member 20 in one embodiment (Fig. 3) is direct contact  
18 between the MEMS device 10 and the contact end 6. In another embodiment (Fig. 4),  
19 connection member 20 is a rigid arm connecting contact end 6 to MEMS device 10.  
20 Preferably, a membrane 22 (Figs. 3 and 4) is disposed at the contact end 6 to be  
21 positioned between the contact end 6 and the cornea of a patient's eye. This  
22 membrane 22 is preferably disposable, non-reactive and bio-compatible with the cornea  
23 and therefore provides a clean, sanitary surface for contact with the eye with each use.

1 In one embodiment shown in Figure 2, the housing and consequently  
2 appearance of the contact tonometer 2 of the present invention is essentially the same  
3 as that shown in U.S. Patent No. 4,747,296 to Feldon et al which is incorporated herein  
4 by reference. However, since the appearance of the contact tonometer 2 is determined  
5 largely by the housing 4, housing 4 may take many forms. The function of housing 4 is  
6 to provide a platform for the contact end 6, to house the MEMS device 10 and the  
7 electronics 12, in one embodiment to provide a platform for the display 16 and, where  
8 the contact tonometer 2 is hand held, to allow the contact tonometer 2 to be gripped and  
9 handled by a user. Consequently, housing 4 may take many forms and shapes so long  
10 as these functions are accomplished. The MEMS device 10 senses the force applied to  
11 the patient's cornea by the contact end 6 of the device and creates an electric signal  
12 related thereto. The MEMS device 10 can be a micro-mechanical device such as those  
13 incorporating moving members such as deflecting micro-cantilevers, deflecting  
14 diaphragms and other micro-machined devices such as are known to the micro-  
15 mechanical art. The MEMS device 10 can also incorporate a moving gas or fluid as is  
16 well understood in micro-fluidic or micro-pneumatic devices. Additionally, the MEMS  
17 device 10 may also incorporate at least one of electrostatic, magnetic, piezoelectric,  
18 electro-magnetic, inertial, pneumatic, hydraulic or thermal micro-actuation mechanisms.  
19 This MEMS technology has already been applied particularly in micro-mechanical  
20 switches and sensors and is therefore well known in the art.

21 As a result, the specific structure associated with such devices is not critical to  
22 the invention. However, the ability of such MEMS devices 10 to detect the force applied  
23 to the contact end 6 and to produce an electrical signal representative of such force is

critical to the invention.

One advantage of using MEMS devices in place of macro-devices or discrete devices in a contact tonometer 2 is that MEMS devices may be fabricated in large numbers through processes analogous to those used in the production of semiconductors. Typically, MEMS devices 10 are produced as packaged chips. These "chip-packages" are usually typical IC-Chip packages made from ceramic, plastic, metal, etc. The fact that such MEMS devices 10 are employed in connection with a contact tonometer 2 and the corresponding performance, cost, packaging and reliability advantages is a key to the invention.

In one embodiment shown in Fig. 3, the contact tonometer 2 has a MEMS device 10 mounted adjacent to the contact end 6 so that connection member 20 is essentially in direct contact between contact end 6 and the MEMS device 10. In this embodiment, the MEMS device 10 is preferably disposed at or near the contact end 6.

In another embodiment shown in Fig. 4, the contact tonometer 2 has a MEMS device 10 mounted proximally away from but mechanically connected to the contact end 6 by the connection member 20. In this embodiment, the mechanical connection may be accomplished through the connection member 20 where connection member 20 is any connection between the contact end 6 and the MEMS device 10 that transfers the force applied to the contact end 6 to the MEMS device 10. One example of such a connection is a rigid arm attached between the contact end 6 and the MEMS device 10. In this embodiment, the MEMS device 10 may be located anywhere within the housing 4 so long as the MEMS device 10 is physically separated from the contact end 6. Here, the connection member 20 transfers motion of the contact end 6 to the MEMS device

1 wherever located.

2 In yet another embodiment shown in Fig. 20, the contact tonometer 2 has a  
3 housing consisting of a first member 150 wherein the contact end 6 and the MEMS  
4 device 10 (Fig. 1) are housed connected to a second member 151 wherein the  
5 electronics 12 (Fig. 1), the power source (14 Fig. 1), activation switch 18 and the display  
6 16 are housed. The connector 152 between first member 150 and second member 151  
7 may be a rigid or preferably flexible. The connector is capable of transmitting electrical  
8 signals from the MEMS device 10 to the electronics 12. In this embodiment the first  
9 member 150 is capable of being attached to the end of a human finger and the second  
10 member 151 is capable of being attached to a human hand. However in other  
11 embodiments, the electronics 12, the activation switch 18 and display 16 or any  
12 combination thereof may also be housed in the first member 150. In yet other  
13 embodiments wherein the connector 152 is flexible, the second member 151 may be  
14 mounted to a table or placed anywhere that is convenient for the operator of the contact  
15 tonometer 2.

16 The MEMS device 10 acts as a transducer or sensor and is formed with MEMS  
17 technology preferably using bulk or etched manufacturing processes to produce a  
18 transducer or sensor of a suitable type. In any of the embodiments of the MEMS device  
19 10 shown, the MEMS device 10 actually measures the force applied to the MEMS  
20 device 10 to the patient's cornea and produces an electrical signal corresponding to  
21 such force. Processing of such electrical signal, such as through the application of an  
22 algorithm operating on the electronics 12 produces a signal representative of the IOP.

23 In one embodiment, the electronics 12 for producing transducer or sensor signals



1 from the MEMS device 10 are fabricated in the MEMS device 10 as is conventional for  
2 integrated circuits. As a result, in this embodiment the MEMS device 10 / electronics 12  
3 combination need only be electrically connected to the source of power 14 and display  
4 16 as described above.

## 5 **MECHANICAL**

6 In a simple form, the MEMS device 10 can be photoetched resistors in a  
7 Wheatstone bridge arrangement in a substrate 26 as is well understood in the art. An  
8 absolute pressure measurement arrangement of such a MEMS device 10 is illustrated  
9 in Fig. 5 wherein an internal chamber 28 is located below a movable membrane or  
10 diaphragm 30. Internal chamber 28 is sealed and held under vacuum. Diaphragm 30 is  
11 connected to contact end 6 in any manner described above. When no force is applied  
12 to diaphragm 30, the substrate 26 is in an equilibrium condition. In this state, the  
13 resistors in the Wheatstone bridge will have a certain resistance which will be the  
14 baseline resistance of the MEMS device 10. When a force is applied to contact end 6  
15 and consequently to diaphragm 30, diaphragm 30 interacts with substrate 26 to place a  
16 different stress on the resistors of the Wheatstone bridge. As a result, the resistance of  
17 the Wheatstone bridge will change. This change is proportional to the force applied to  
18 diaphragm 30 from the contact end 6. Consequently, the force applied by the contact  
19 end 6 on the patient's cornea will produce a change in the resistance of the Wheatstone  
20 bridge in a way that is highly correlated to such force.

21 A gauge pressure measurement arrangement of MEMS device 10 is illustrated in  
22 Fig. 6 wherein the substrate 26, internal chamber 28 and diaphragm 30 have been  
23 modified to provide a passage 32 connecting internal chamber 28 to ambient

1 atmospheric pressure. The operation of this MEMS device 10 is as described above in  
2 connection with the embodiment shown in Fig. 5. In this embodiment, the difficulty of  
3 maintaining a vacuum within the internal chamber 28 is eliminated. However, in the  
4 unstressed condition, the MEMS device 10 must be allowed to come to an equilibrium  
5 condition before an IOP measurement can be taken. This equilibrium condition is  
6 dependent, in part, on the ambient atmospheric pressure which is constantly changing.  
7 However, the change in ambient pressure is so small over the time span needed to take  
8 an IOP measurement that once the MEMS device 10 has reached an equilibrium  
9 condition and the electronics 12 is calibrated to indicate "zero" pressure, subsequent  
10 IOP measurements will be highly accurate.

11 A sealed gauge pressure measurement arrangement of MEMS device 10 is  
12 illustrated in Fig. 7 wherein the substrate 26, internal chamber 28 and diaphragm 30 are  
13 as described in connection with the embodiment of Fig. 5 with the exception that instead  
14 of a vacuum within internal chamber 28, a fixed common reference pressure is placed  
15 within internal chamber 28. This embodiment eliminates the difficulty of providing a  
16 vacuum within the internal chamber 28 and also eliminates the need to allow the MEMS  
17 device 10 to equilibrate before each use to accommodate the changing atmospheric  
18 pressure.

## 19 **PIEZOELECTRIC**

20 An example of a MEMS device 10 using a piezoelectric transducer for use with  
21 the contact tonometer 2 is shown in Figs. 8-10 and described in detail below. Where  
22 the MEMS device 10 is a piezoelectric arrangement, when the piezoelectric elements  
23 are strained by an external force, displaced electrical charge accumulates on opposing

1 surfaces. When piezoelectric elements are strained by an external force, displaced  
2 electrical charge accumulates on opposing surfaces. Fig. 11 schematically shows the  
3 displacement of electrical charge due to the deflection of the lattice in a naturally  
4 piezoelectric quartz crystal. The larger circles having the notation "Si<sup>+</sup>" represent silicon  
5 atoms while the smaller circles having the notation "O<sup>-</sup>" represent oxygen. As shown in  
6 Figure 11, when a force is applied to the crystal, charge of opposite polarity  
7 accumulates on opposite sides of the crystal.

8 Many different sizes and shapes of piezoelectric materials can be used in  
9 piezoelectric sensors for MEMS device 10. Acting as true precision springs, different  
10 element configurations, such as compression, flexural and shear, offer various  
11 advantages and disadvantages, flexural being preferred for the present invention. With  
12 stiffness values on the order of 15E6 psi (104E9 N/m<sup>2</sup>), which is similar to that of many  
13 metals, piezoelectric materials produce a high output with very little strain. In other  
14 words, piezoelectric sensing elements have essentially no deflection and are often  
15 referred to as solid-state devices. For this reason, piezoelectric sensors are rugged and  
16 feature excellent linearity over a wide amplitude range. Crystalline quartz, either in its  
17 natural or high-quality, reprocessed form, is one of the most sensitive and stable  
18 piezoelectric materials available and is the preferred material for a MEMS device 10 in  
19 this embodiment.

20 Piezoelectric materials can only measure dynamic or changing events.  
21 Piezoelectric sensors are not able to measure a continuous static event as would be the  
22 case with measuring inertial guidance, barometric pressure or weight. As a result, the  
23 electronics associated with the piezoelectric MEMS device 10 of this embodiment must

1 be able to detect the change of status of the MEMS device 10. While static events will  
2 cause an initial output due to a change from the previous condition to the current  
3 condition, this signal will slowly decay or drain away based on the piezoelectric material  
4 or attached electronics time constant. This time constant corresponds with a first order  
5 low pass filter and is based on the capacitance and resistance of the device. This low  
6 pass filter ultimately determines the low frequency cut-off or measuring limit of the  
7 device. In the preferred embodiment of the invention, the MEMS device 10 should have  
8 a time constant that is about equal to the time it takes for the clinician to tap the  
9 patient's cornea with the contact tonometer 2. Also, the cutoff frequency should be high  
10 enough to allow complete measurement of the IOP.

11 An example of a highly sophisticated MEMS device 10 using a piezoelectric  
12 transducer for use with the contact tonometer 2 is shown in Figs. 8-10 wherein both  
13 shear and normal forces can be measured. The MEMS device 10 in these  
14 embodiments could be fashioned after that described in Kane, B. J., et. al., "Force-  
15 Sensing Microprobe for Precise Stimulation of Mechanosensitive Tissues," IEEE  
16 Transactions on Biomedical Engineering, vol. 42, no. 8, Aug. 1995, pp. 745 – 750,  
17 which is incorporated herein by reference. The embodiments of Figs. 8-10 provide an  
18 extremely accurate means to measure IOP by assuring normality of the transducer  
19 surface to the eye.

20 In the embodiment of the invention shown in Figs. 8a, 9a and 10a, the MEMS  
21 device 10 is a piezoelectric device. Acting as true precision springs, the different  
22 element configurations shown in Figures 8-10 offer various advantages and  
23 disadvantages. In Figs. 8-10 schematic diagrams labeled Figs. 8b, 9b and 10b

1 represent in shaded area the piezoelectric crystals while the arrows indicate how the  
2 piezoelectric crystal material is being stressed.

3 In the embodiment shown in Fig. 8, the MEMS device 10 includes a piezoelectric  
4 crystal 40. The crystal 40 is placed between and in contact with a first face 42 and a  
5 second face 44. Crystal 40 has a central slot 46 that runs essentially parallel to both  
6 first face 42 and second face 44. First face 42 is either in direct contact with the contact  
7 end 6 or is in mechanical contact with contact end 6 through a connection member 20  
8 as described above. In this way, force of the contact tonometer 2 contacting the  
9 patient's eye is directed to contact end 6 and then either directly or indirectly to the first  
10 face 42. Second face 44 is anchored to the contact tonometer 2 so that it provides a  
11 steady base for crystal 40. When a force is applied to the contact end 6, and therefore  
12 also applied to the first face 42, the force is applied to the crystal 40. In response to the  
13 application of the force, crystal 40 will attempt to move into more firm contact with the  
14 second face 44. However, because second face 44 is anchored to the contact tonometer  
15 20, second face 44 will resist movement due to the force applied to crystal 40. As a  
16 result, crystal 40 will be stressed and charge will accumulate on opposite sides of the  
17 central slot 46 (Fig. 8b). The accumulated charge is collected on opposite sides of the  
18 central slot 46 and, when connected to electronics 12, produces a signal representative  
19 of the force applied to the crystal 40 which, in turn, corresponds to the force applied to  
20 the contact end 6 which in turn corresponds to the patient's IOP.

21 In the embodiment shown in Fig. 9, the MEMS device 10 also includes a  
22 piezoelectric crystal 40. The crystal 40 is placed over a pivot point 48 on a base 50.  
23 Crystal 40 in this embodiment has a first side 52 and a second side 54 on either side of

1 the pivot point 48 and a top 56 and a bottom 58. Either or both first side 52 or second  
2 side 54 is in either direct contact with the contact end 6 on the top 56 or is in mechanical  
3 contact with contact end 6 through a connection member 20 as described above  
4 connected to the contact end 6 on one end and the top 56 on the other end. In this  
5 way, force of the contact tonometer 2 contacting the patient's eye is directed to contact  
6 end 6 and then either directly or indirectly to either or both of first side 52 or second side  
7 54. Base 50 is anchored to the contact tonometer 2 so that it provides a steady base  
8 for pivot point 48 where pivot point 48 contacts the bottom 58 of crystal 40. When a  
9 force is applied to the contact end 6, and therefore also applied to the first side 52,  
10 second side 54 or both, contact between the bottom 58 of crystal 40 and the pivot point  
11 48 prevents the part of crystal 40 between first side 52 and second side 54 from  
12 moving. As a result, crystal 40 flexes around the pivot point 48. As crystal 40 is  
13 stressed on either side of the pivot point 48, opposite charge accumulates on the top 56  
14 and bottom 58 of crystal 40 (Fig. 9b). The accumulated charge is collected from top 54  
15 and bottom 58 and, when connected to electronics 12, produces a signal representative  
16 of the force applied to the crystal 40 which, in turn, corresponds to the force applied to  
17 the contact end 6 which in turn corresponds to the patient's IOP.

18 In the embodiment shown in Fig. 10, the MEMS device 10 again includes a  
19 piezoelectric crystal 40. In this embodiment, crystal 40 is mounted on a central cylinder  
20 60 that is rigidly attached to a base 50 and extends through crystal 40. Crystal 40 in  
21 this embodiment also has a first side 52 and a second side 54 on either side of the  
22 central cylinder 60 and a top 56. Top 56 is in either direct contact with the contact end 6  
23 or is in mechanical contact with the contact end 6 as described above. First side 52 and

1 second side 54 are in direct contact with the top 56. Base 50 is anchored to the contact  
2 tonometer 2 so that it provides a steady and relatively immovable base for central  
3 cylinder 60. Central cylinder 60 supports crystal 40 and acts as a pivot point for crystal  
4 40 as torque is applied to crystal 40 through force applied from the contact end 6 to the  
5 top 56.

6 In this way, force of the contact tonometer 2 contacting the patient's cornea is  
7 directed to contact end 6 and then either directly or indirectly to either or both of first  
8 side 52 or second side 54 which in turn causes crystal 40 to be flexed or torqued around  
9 central cylinder 60. But, because central cylinder 60 is relatively immovable, crystal  
10 cannot move but instead is compressed on either first side 52, second side 54 or both.  
11 This compression causes charge to be distributed on opposite faces of crystal 40. As  
12 crystal 40 is stressed around central cylinder 60, opposite charge accumulates on the  
13 top 56 and bottom 58 of crystal 40 (Fig. 10b). The accumulated charge is collected  
14 from top 56 and bottom 58 and, when connected to electronics 12, produces a signal  
15 representative of the force applied to the crystal 40 which, in turn, corresponds to the  
16 force applied to the contact end 6 which in turn corresponds to the patient's IOP. The  
17 advantage of this embodiment is that it offers a well-balanced blend of low sensitivity to  
18 base strain and low sensitivity to thermal inputs.

## 19 **OPTICAL**

20 A MEMS device 10 using optical pressure transducer/sensor arrangements, such  
21 as that shown in Fig. 12, can be used with the contact tonometer 2 to detect the effects  
22 of minute motions due to changes in pressure and generate a corresponding electronic  
23 output signal to pass to electronics 12. A source diode 62 is used as a light source that

1 projects light toward a measuring diode 64 and a reference diode 66. Source diode 62  
2 may be a light emitting diode (LED) that emits visual or infrared light. A vane 68 is  
3 attached to contact end 6 and moves as contact end 6 moves in contact with the  
4 patient's cornea. Vane 68 may be either connected directly to contact end 6 as  
5 described above or, as shown in Fig. 12, contact end 6 may be a piston 70 that is  
6 placed in a bore 72. In this embodiment, vane 68 is located on a diaphragm 74. A  
7 chamber 76 is formed between diaphragm 74 and bore 72 that is filled with a fluid. As  
8 piston 70 moves in response to the force applied by the contact tonometer 2 on a  
9 patient's cornea, pressure builds within the chamber 76. This pressure causes the  
10 diaphragm 74 to deflect with in turn causes the vane to move in the light path of light  
11 source 62. As vane 68 moves with movement of contact end 6, in either the  
12 embodiment of direct contact with contact end 6 or in the embodiment shown in Fig. 12,  
13 vane 68 blocks more and more of the light from source diode 62 as it is directed toward  
14 the measuring diode 64 and thus changes the amount of light received by measuring  
15 diode 64.

16 This optical MEMS device 10 embodiment may also compensate for aging of the  
17 source diode 62 through the use of by means of the reference diode 66. Reference  
18 diode 66 is located so that it is never blocked from receiving light from the source diode  
19 62 by the vane 68. Because the reference diode 66 is never blocked by the vane 68,  
20 any degradation of the signal received by the reference diode 66 will be due to  
21 deterioration, such as by the build-up of dirt or other coating materials on the optical  
22 surfaces or aging of the source diode 62. Consequently, the signal produced by the  
23 source diode 62 may be used as a baseline to which the signal produced by the



measuring diode 64 can be compared.

The optical MEMS device 10 embodiment is relatively immune to temperature effects because the source diode 62, measurement diode 64 and reference diode 66 are affected equally by changes in temperature. Moreover, because the amount of movement of the contact end 6 required to make measurements is very small (typically under 0.5 mm), hysteresis and repeatability errors are nearly zero. An optical MEMS device 10 such as described herein also does not require much maintenance, has excellent stability and is designed for long-duration measurements and are available with ranges from 5 psig to 60,000 psig (35 kPa to 413 MPa) and with 0.1% full scale accuracy.

#### **RESONANT / VIBRATION**

MEMS device 10 can be of the resonant/vibration type. In such a MEMS device 10, a structure is caused to resonate at its natural frequency and this frequency is modulated as a function of the input parameter, in this case the force applied to the patient's cornea. A MEMS device 10 according to this embodiment is shown in Fig. 13. MEMS device 10 in this embodiment includes resonant cylinder 78 preferably made of a flexible metallic bellows, an outer cylinder 80 that surrounds the resonant cylinder 78, a cylinder driver and pickup 82 and an input channel 84.

As stated above, resonant cylinder 78 may be made of a metallic bellows. The flexible metallic bellows of resonant cylinder 78 is used to modulate the force applied to the MEMS device 10 as a function of the pressure applied to MEMS device 10 through contact with the contact end 6 and the patient's cornea. It is preferable to use high-elasticity, low-creep and low hysteretic materials in the fabrication of the resonant

1 cylinder 78. This results in a highly stable and high-resolution measurement method.  
2 Resonant cylinder 78 is either made of a ferromagnetic material or has pieces of  
3 ferromagnetic material placed in or on it to allow it to be driven at a resonance  
4 frequency as will be described hereafter.

5 Preferably, a vacuum is placed between the resonant cylinder 78 and the outer  
6 cylinder 80. This vacuum separates resonant cylinder 78 from outer cylinder 80 to  
7 decouple movement of resonant cylinder 78 from the outer cylinder 80. The vacuum  
8 here is preferably a high-quality internal vacuum around the resonant cylinder 78  
9 thereby eliminating the viscous damping effects that an internal gas environment would  
10 present to the resonating resonant cylinder 78 and to reduce the drive power  
11 requirements as will be explained hereafter in connection with the cylinder driver and  
12 pickup 82. This internal vacuum also prevents ideal gas thermal expansion forces that  
13 would act upon the resonant cylinder 78 and the large variable effects that airborne  
14 moisture would cause.

15 The interior of the resonant cylinder 78 and the input channel 84 is preferably  
16 filled with fluid but could also be filled with a gas. The input channel 84 is connected to  
17 the connection member 20. Connection member 20 in this embodiment is fashioned so  
18 that a portion of connection member 20 extends into the input channel 84 and acts as a  
19 piston. As a result, as the connection member 20 is moved as a result of contact  
20 between the connection member 20 and the patient's cornea, the portion of connection  
21 member 20 in input channel 84 interacting with the fluid within input channel 84 causes  
22 the pressure of the fluid within the resonant cylinder 78 to increase.

1 In this embodiment of the MEMS device 10, the resonant cylinder 78 is caused to  
2 oscillate at its resonance frequency by the "driver" portion of the cylinder driver and  
3 pickup 82. The resonance frequency is the frequency at which maximum mechanical  
4 output (vibration) occurs with a minimum energy input. For this reason, the total energy  
5 required to cause the resonant cylinder 78 to vibrate at its resonance frequency is small.  
6 The resonance frequency is therefore the frequency of motion at which maximum  
7 efficiency results for vibration of the resonant cylinder 78. Changes in the resonant  
8 frequency will occur due to the different pressures induced within the resonant cylinder  
9 78 as a result of contact between the connection member 20 and a patient's cornea as  
10 described above.

11 The cylinder driver and pickup 82 performs the double function of both causing  
12 the resonant cylinder 78 to vibrate and also sensing the vibration of resonant cylinder  
13 78. This is preferably accomplished by either electromagnetic or piezoelectric methods  
14 in an analogous method to electric guitar pickups. Here, as shown in Figure 14, at least  
15 one coil 86 of insulated wire is placed near the surface of resonant cylinder 78 opposite  
16 where the connection member 20 contacts the input channel 84. The coil 86 has a  
17 central axis 88 around which the coil 86 is formed. The central axis 88 is oriented  
18 perpendicular to the outer surface of resonant cylinder 78. In a preferred embodiment,  
19 a permanent magnet 90 is placed through the coil 86 so that a pole 92 of the magnet 90  
20 extends away from the coil 86. In alternate embodiments, the magnet 90 may be  
21 placed below coil 86 with a soft iron core placed within the coil 86. Also, it may be  
22 desirable to be able to move the magnet 90 closer to or away from the surface of the  
23 resonant cylinder 78 to "tune" the cylinder driver and pickup 82. Also, it may be

desirable to surround the coils with some sort of an electromagnetic shield such as a metal case or isolating tape.

Direct current is passed through the coil 86 thereby creating a magnetic field with lines of magnetic flux passing through the center of coil 86. This magnetic field interacts either directly with the material of resonant cylinder 78 if this material is ferromagnetic or with the piece or pieces of ferromagnetic material placed on or in the material making up the resonant cylinder 78. By varying the electric current passed through the coil 86, the pull on the resonant cylinder 78 is varied. By pulsing the application of electric current through the coil 86 the resonant cylinder 78 can be made to vibrate. When the application of current through the coil 86 coincides with the resonant frequency of the resonant cylinder 78, the amplitude of the vibration of resonant cylinder 78 will be the largest.

The "pickup" portion of cylinder driver and pickup 82 also senses the movement of the resonant cylinder 78 as resonant cylinder 78 vibrates in response to the application of electric current to coil 86 as described above. The movement of the ferromagnetic material of resonant cylinder 78 in the magnetic field of the permanent magnet causes the magnetic flux through the coil 86 to change. Since the coil 86 is a good conductor, the change in magnetic flux is opposed in the coil 86 by the induction of an alternating current. The change in magnetic field that is created from the AC current is opposite to that of the change in magnetic field in the coil 86 due to a principle known as Lenz's Law. The reason for the induction of an alternating current in the coil 86 rather than a direct current is due to the motion of the of the vibrating resonant cylinder 78 as the surface of the resonant cylinder moves both towards and away from

1 the pole 92 of the pickup in the same way that the voltage of an AC current increases  
2 and decreases.

3 As the surface of resonant cylinder 78 moves closer to the pole 92, the magnetic  
4 flux within coil 86 increases while the magnetic flux in coil 86 decreases while the  
5 surface of the resonant cylinder 78 moves farther away from the pole 92. The magnetic  
6 field lines flow through the coil 86 and a portion of the surface of resonant cylinder 78.  
7 With the surface of resonant cylinder 78 at rest, the magnetic flux through the coil 86 is  
8 constant. But, as coil 86 is activated to magnetically couple with resonant cylinder 78,  
9 the flux changes. This change of flux induces an electric voltage in the coil 86. This  
10 vibrating resonant cylinder 78 induces an alternating voltage at the frequency of  
11 vibration, where the voltage is proportional to the velocity of the motion of the surface of  
12 resonant cylinder, not the amplitude of such vibration. Furthermore, the voltage  
13 depends on the material, thickness and magnetic permeability of the resonant cylinder  
14 78 and the strength of the magnetic field created by coil 86 and the distance between  
15 the magnetic pole 92 and the resonant cylinder 78.

16 From an electrical standpoint, the pickup portion of the cylinder driver and pickup  
17 82 is shown in Fig. 1518. The windings of coil 86 have an inductance  $L$  in series with  
18 an resistance  $R$  and is parallel to both a winding capacitance  $C$ . Of these electrical  
19 components, by far the most important quantity is the inductance which it depends on  
20 the number of windings, the magnetic material in the coil and the geometry of the coil  
21 86. Although present, the resistance doesn't have much influence and for practical  
22 purposes can be neglected. As described above, when the resonant cylinder 78 is  
23 vibrating, an AC voltage is induced in the coil 86. The capacitance  $C$  is the sum of the

1 winding capacitance of the coil and the capacitance of the wiring connecting coil 86 to  
2 the electronics that powers the coil 86 and processes the information sensed by coil 86.  
3 The resonant frequency of coil 86 depends on both the inductance  $L$  and the  
4 capacitance  $C$ .

5         Although the cylinder driver and pickup 82 described above has been described  
6 with a single coil 86, such single coils are sensitive to magnetic fields generated by  
7 transformers, fluorescent lamps, and other sources of interference and are prone to pick  
8 up hum and noise from these sources. Therefore, it is preferably that instead of a single  
9 coil for coil 86, dual coils that are electrically out of phase, such as those used in  
10 "humbucking" pickups for guitars, are used to minimize this interference. Because  
11 these coils for coil 86 are electrically out of phase, common-mode signals (i.e. signals  
12 such as hum that radiate into both coils with equal amplitude) cancel each other.

13         The "driver" and "pickup" of cylinder driver and pickup 82 are connected in a  
14 closed-loop system whereby the "driver" portion of cylinder driver and pickup 82 can be  
15 driven in response to the sensed vibration of the metallic resonant cylinder 78 by the  
16 "pickup" portion of the cylinder driver and pickup 82. Because this is a closed loop  
17 system, the frequency that the "driver" drives the resonant cylinder 78 can be adjusted  
18 to the frequency requiring the minimum energy to drive the resonant cylinder 78. This  
19 minimum energy is found at its most mechanically-efficient frequency or "maximum-Q"  
20 response point. This frequency is the resonant frequency for resonant cylinder 78.

21         Counter circuitry then counts the oscillator output over some defined time-  
22 averaging window. Such circuitry as is well known in the quartz watch industry can be  
23 used to detect the resonant frequency. The frequency response of the resonant sensor

1 is therefore a direct function of the number of time-averaged samples provided per  
2 second and is generally low. Alternatively, the frequency of the resonant structure can  
3 be measured utilizing a period measurement system to provide a much wider  
4 measurement bandwidth. Period measurement systems rely upon a second internal  
5 time base operating at a much higher frequency than the resonant structure to provide  
6 adequate period resolution.

## 7 **FLUID**

8 MEMS device 10 can be of the fluidic type. In such devices, a force, such as that  
9 applied by the contact end 6 as it contacts a patient's cornea, is applied to a gas or fluid  
10 contained in a chamber. The force is transmitted through the gas or fluid to a moving  
11 member. The moving member of such MEMS devices 10 can move in response thereto  
12 as, for example, by distortion, deformation, translation, deflection, rotation, torsion or  
13 other motion. This motion is then detected by, for example, a strain gauge to produce  
14 the electrical signal representative of the force applied.

15 In such a MEMS device 10, shown in Fig. 16, a substrate 94 having a top surface  
16 96 has a series of microfluidic channels 98 micro-machined, formed or cut in its top  
17 surface 96. The channels 98 have a central inlet 100 and two outlets 102. The  
18 channels 98 function as a pressure drop / pulse attenuator for fluid flow through the  
19 MEMS device 10. Central inlet 100 forms a chamber 104 near the outermost edge of  
20 substrate 94. A piston 70 such as is described in connection with the embodiment of  
21 Figure 13 is placed in a fluid-tight position in chamber 104 and is connected to the  
22 contact end 6 either directly or through the connecting member 20. In this way,  
23 movement of the contact end 6 causes the piston 70 to move within the chamber 104.

1 The chamber 104 is filled with a fluid. As the contact end 6 moves in response to the  
2 force applied by the applanation tonometer 2 to the patient's cornea, the piston 70 is  
3 moved into the chamber 104 causing an increase in fluid pressure inside the chamber  
4 104. The fluid flows from the chamber 104 through the central inlet 100, through the  
5 channels 98 and out through the two flanking outlets 102 at a reduced pressure. Since  
6 the flow rate is directly related to the pressure applied to the contact end 6, measuring  
7 the flow rate by any of the commonly known methods for measuring the flow rate  
8 provides a direct correlation to the pressure applied to the contact end 6 and thus to the  
9 patient's IOP.

10 As an example of the size of the MEMS device 10 in this embodiment, the MEMS  
11 device 10 is approximately 100 x 120  $\mu\text{m}$ , with a channel depth of 10  $\mu\text{m}$ . The MEMS  
12 device 10 also includes a lid 106 to seal the top of the MEMS device 10. This lid 106 is  
13 made by sealing another chip of corresponding dimensions to the substrate onto the top  
14 surface 96 of the substrate 94 thus making a so-called "flip chip package".

## 15 **CAPACITIVE**

16 MEMS device 10 may also be a capacitive device. Such a MEMS device 10 is  
17 shown in Fig. 17. The MEMS device 10 of Fig. 17 includes a first plate 108 and a  
18 second plate 110 that are parallel to each other and form a capacitor. The first plate  
19 108 is fixed to a ceramic diaphragm 112 that is in contact, either directly or through  
20 connection member 20, with the contact end 6. Diaphragm 112 flexes in response to  
21 force changes applied to the contact end 6. The second plate 110 is attached, with a  
22 rigid glass seal, to a ceramic substrate 114 that is insensitive to pressure changes. As  
23 the force applied to the contact end 6 varies (Fig. 17b), the diaphragm 112 flexes and



1 the distance between the first plate 108 and second plate 110 changes. This MEMS  
2 device 10 thus produces a variable capacitor that is highly stable and reliable. The  
3 variable capacitor then becomes part of, for example, an oscillator circuit whose  
4 frequency is proportional to the force of the contact end 6 on the patient's cornea.

## 5 **MAGNETIC**

6 MEMS device 10 may also be a magnetic device. Such a MEMS device 10 is  
7 shown in Fig. 18. The MEMS device 10 of Fig. 18 forms a magnetic circuit wherein the  
8 contact end 6 is connected to a spring member 116. Application of a force to the  
9 contact end 6 causes mechanical deflection of spring member 116 as a function of the  
10 force. The MEMS device 10 of this embodiment includes a spring member 116 made of  
11 a magnetic, high-permeability material. Spring member 116 is centrally located  
12 between two coils 118 and 120 made of insulated wire. The coils 118, 120 are  
13 surrounded by and magnetically isolated from each other by insulating barriers such as  
14 nonmagnetic welded stainless steel barriers 122. Coils 118, 120 are electrically  
15 connected as part of an oscillator circuit. As the inductance of coils 118, 120 changes  
16 due to movement of contact end 6, the oscillation frequency of the oscillator circuit  
17 changes.

18 The electrical configuration of this MEMS device 10 is that of an inductive half-  
19 bridge. This half-bridge is driven by an alternating voltage source in the range typically  
20 of 1 KHz to 10 KHz. The centrally-disposed spring member 116 results in an inductive  
21 push-pull arrangement where deflection of the spring member 116 reduces the  
22 inductance of one coil (e.g. coil 118) and increases the inductance of the other (i.e. coil  
23 120) creating a difference in coil impedance. The variation in the magnetic reluctance

1 produces the effective inductance modulation as a function of the parameter input, in  
2 this case, the force applied to the contact end 6 by the patient's cornea.

3 A variant of the embodiment of Fig. 18 is shown in Fig. 19. In this  
4 embodiment MEMS device 10 includes a first chamber 124 and a second  
5 chamber 126 formed on either side of spring member 116. Also, contact end 6 is  
6 not attached directly to spring arm 116. Instead, contact end 116 is attached to a  
7 piston 70 that is placed in first chamber 124 in a fluid-tight manner. Second  
8 chamber 126 is exposed to either a fixed or ambient pressure. This fixed or  
9 ambient pressure becomes the reference pressure for the MEMS device 10 in  
10 this embodiment. First chamber 124 is exposed to pressure created by the  
11 contact end 6 moving piston 70 in response to force applied to contact end 6 as  
12 the contact tonometer 2 is moved into contact with the patient's cornea. As can  
13 be seen, as the contact end 6 is moved into contact with the patient's cornea, a  
14 pressure difference will result between first chamber 124 and second chamber  
15 126. This pressure differential will cause the spring member 116 to deflect from  
16 its resting position to a position in response to the differential pressure.  
17 Specifically, the increase in pressure in first chamber 124 will cause a difference  
18 in pressure between the first chamber 124 and the second chamber 126 that will  
19 move the spring member 116 towards the coil 118. This will result in modulation  
20 of the inductance (L) of the two coils 118, 120 which will be correlated by suitable  
21 electronics 12 to indicate the patient's IOP.

22 The following documents/products are incorporated herein by reference to  
23 provide exemplary disclosures of MEMS technology for use with the present invention:

English, J.M. et.al., "Wireless Micromachines Ceramic Pressure Sensors," IEEE, 1999, pp. 511-516; U.S. Patent Application Publication No. 2002/0121135 A1 to Rediniotis et.al; Kulsite XCS-062 differential pressure transducer using a fully active Wheatstone bridge on a silicone membrane; S. Sugiyama et. al. "Micro-diaphragm Pressure Sensor," IEEE Int. Electron Devices Meetings, 1986, pp.184-7, and H. Tanigawa et.al; "MOS Integrated Silicon Pressure Sensor, "IEEE Trans Electron Devices, Vol. ED-32, No. 7, pp. 1191 - July 15, 1985; U.S. Patent Application Publication No. 2002/0115920 A1 to Rish et al; U.S. Patent Application Publication No. 2002/0073783 A1 to Wilner et al; U.S. Patent Application Publication No. 2002/0049394 A1 to Roy et al; U.S. Patent Application Publication No. 2002/0045921 A1 to Wolinsky et al; U.S. Patent Application Publication No. 2002/0029814 A1 to Unger et al; U.S. Patent Application Publication No. 2002/0029639 A1 to Wagner et al; U.S. Patent No. 6,408,878 to Under et al; U.S. Patent No. 6,367,333 B1 to Bullister et al; U.S. Patent No. 6,341,528 B1 to Hoffman et al; U.S. Patent No. 6,183,097 B1 to Scref et al; U.S. Patent No. 6,460,234 B1 to Gianchandani; and U.S. Patent No. 6,188,477 B1 to Pu et al. The MEMS transducer/sensor technology can sense pressure based on capacitive, electrostriction, magnetic, electromagnetic, thermoelastic, piezoelectric, piezoresistive, optical, resonance or other suitable effects.

The contact tonometer 2 of the present invention has been described herein as a handheld device. However, it is also within the scope of the invention for the contact tonometer 2 to be in a desktop or benchtop form. In such embodiments, the housing 4 would be attached to or include a base that rests on the desk or bench. In this embodiment the contact end 6 would be presented to contact a patient's cornea by

1 mechanically moving the contact end 6 into such contact. Such means for moving the  
2 contact end are well within the scope of normal mechanical engineering so are not  
3 presented in detail at this time.

4 Inasmuch as the present invention is subject to various modifications and  
5 changes in detail that will be clear to those skilled in the art, it is intended that all subject  
6 matter discussed above and shown in the accompanying drawings be used as  
7 examples of the present invention and therefore should not be taken in a limiting sense.  
8 It is clear that changes and modifications to the description given herein including the  
9 drawings can be made and still be within the scope of the invention.

10